



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0578; FRL-9336-7]

Indoxacarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indoxacarb in or on egg, poultry fat, poultry meat, and poultry meat byproducts. E.I. du Pont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0578. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket

at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Julie Chao, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8735; e-mail address: *chao.julie@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0578 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of

your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0578, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 26, 2011 (76 FR 53372) (FRL-8884-9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7873) by E.I. du Pont de Nemours and Company, 1007 Market Street, Wilmington, DE 19898-0001. The petition requested that 40 CFR 180.564 be amended by establishing tolerances for residues of the insecticide indoxacarb, (*S*)-methyl-7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)-phenyl]amino]carbonyl]indeno[1,2-e] [1,3,4]oxadiazine-4a(3*H*)-carboxylate, its *R*-enantiomer, (*R*)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy) phenyl]amino]carbonyl]indeno [1,2-e] [1,3,4]

oxadiazine-4a(3*H*)- carboxylate, and the metabolites: IN-JT333: Methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]-amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3*H*)-carboxylate; IN-KT319: (*E*)-methyl 5-chloro-2,3,-dihydro-2-hydroxy-1-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]-carbonyl]hydrazono]-1*H*-indene-2-carboxylate; IN-JU873: Methyl 5-chloro-2,3-dihydro-2-hydroxy-1-[[[[4-(trifluoromethoxy)-phenyl]amino]carbonyl]hydrazono]-1*H*-indene-2-carboxylate; IN-KG433: Methyl 5-chloro-2,3,-dihydro-2-hydroxy-1-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]-hydrazono]-1*H*-indene-2-carboxylate; and IN-KB687: Methyl [4-(trifluoromethoxy)phenyl]carbamate, in or on egg at 0.2 parts per million (ppm); poultry, fat at 0.2 ppm; poultry, meat at 0.06 ppm; and poultry, meat byproducts at 0.06 ppm. That notice referenced a summary of the petition prepared by E.I. du Pont de Nemours and Company, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children

to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for indoxacarb including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with indoxacarb follows.

In the **Federal Register** of July 10, 2009 (74 FR 33159) (FRL-8424-9), EPA published a Final Rule establishing tolerances for residues of the insecticide indoxacarb in or on various beet commodities and the bushberry subgroup 13-07B. These tolerances had been requested in PP 8E7324. When the Agency conducted the risk assessment in support of the July 10, 2009 tolerance action, it also considered residues of indoxacarb, its R-enantiomer, and its metabolites IN-JT333, IN-KT319, IN-JU873, IN-KG433, and IN-KB687 in or on egg; poultry, fat; poultry, meat; and poultry, meat byproducts. These tolerances were evaluated by EPA based on the results of a previously submitted and accepted poultry feeding study; however, because of a deficiency related to a poultry storage stability study, EPA was not able to establish tolerances on egg and poultry commodities. Since that time, the registrant has provided an acceptable poultry storage stability study, which supports the establishment of tolerances on egg; poultry, fat; poultry, meat; and poultry, meat byproducts. Detailed considerations regarding EPA's resolution of these data deficiencies are discussed in the document, “Indoxacarb. Petition

for the Establishment of Permanent Tolerances on Poultry Commodities and Submission of Storage Stability Data for Poultry Commodities in Response to HED Memorandum DP#297936, 9/22/04,” which is available at <http://www.regulations.gov> in docket EPA-HQ-OPP-2011-0578.

Since EPA considered the additional uses proposed by PP 1F7873 in its most recent risk assessments, establishing tolerances on these commodities will not change the estimated aggregate risks resulting from use of indoxacarb, as discussed in the **Federal Register** of July 10, 2009 (74 FR 33159) (FRL-8424-9). In that action, EPA concluded that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to indoxacarb residues. Refer to the July 10, 2009 (74 FR 33159) (FRL-8424-9) **Federal Register** document, available at <http://www.regulations.gov> in docket EPA-HQ-OPP-2008-0271, for a detailed discussion of the aggregate risk assessments and determination of safety. The findings in that action apply with equal force here and are adopted by EPA in this rulemaking. Accordingly, EPA concludes that aggregate exposure to indoxacarb will be safe for the general population, including infants and children.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC)/column switching/ultraviolet (UV) method AMR 2712–93 with confirmation/specificity provided by gas chromatography (GC)/mass-selective detector method AMR 3493–95, Supplement No. 4) is available to enforce the tolerance expression.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for indoxacarb in or on eggs at 0.02 mg/kg; poultry meat at 0.01 mg/kg; and poultry, edible offal at 0.01 mg/kg. These MRLs are lower than the poultry tolerance levels determined appropriate for indoxacarb in the United States. The U.S. residue definition for poultry commodities includes indoxacarb, its R-enantiomer, and five metabolites, whereas the Codex residue definition includes only indoxacarb and its R-enantiomer. Because the Codex residue definition and evaluation procedures for livestock commodities differ from those of the United States harmonization of U.S. tolerances with Codex MRLs is not possible for poultry commodities.

V. Conclusion

Therefore, tolerances are established for residues of indoxacarb, (*S*)-methyl-7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)-phenyl]amino]carbonyl]indeno[1,2-e] [1,3,4]oxadiazine-4a(3*H*)-carboxylate; its *R*-enantiomer (*R*)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy) phenyl]amino]carbonyl]indeno [1,2-e] [1,3,4] oxadiazine-4a(3*H*)-carboxylate; and the metabolites: IN-JT333: Methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]-amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3*H*)-carboxylate; IN-KT319: (*E*)-methyl 5-chloro-2,3,-dihydro-2-hydroxy-1-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]-carbonyl]hydrazono]-1*H*-indene-2-carboxylate; IN-JU873: Methyl 5-chloro-2,3-dihydro-2-hydroxy-1-[[[4-(trifluoromethoxy)-phenyl]amino]carbonyl]hydrazono]-1*H*-indene-2-carboxylate; IN-KG433: Methyl 5-chloro-2,3,-dihydro-2-hydroxy-1-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]-hydrazono]-1*H*-indene-2-carboxylate; and IN-KB687: Methyl [4-(trifluoromethoxy)phenyl]carbamate, in or on egg at 0.20 parts per million (ppm); poultry, fat at 0.20 ppm; poultry, meat at 0.06 ppm; and poultry, meat byproducts at 0.06 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule

has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal*

Governments (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 1, 2012

Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.564 is amended by adding the designation “(1)” after the heading “General” in paragraph (a), and by adding paragraph (a)(2) to read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

(a) *General.* (1) ***

(2) Tolerances are established for residues of indoxacarb, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of indoxacarb, (S)-methyl-7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)-phenyl]amino]carbonyl]indeno[1,2e] [1,3,4]oxadiazine-4a(3H)-carboxylate, its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy) phenyl]amino]carbonyl]indeno [1,2-e] [1,3,4]oxadiazine-4a(3H)- carboxylate, and the metabolites: IN-JT333, methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]-amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate; IN-KT319, (E)-methyl 5-chloro-2,3,-dihydro-2-hydroxy-1-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]-carbonyl]hydrazono]-1H-indene-2-carboxylate; IN-JU873, methyl 5-chloro-2,3-dihydro-2-hydroxy-1-[[[4-(trifluormethoxy)-phenyl]amino]carbonyl]hydrazono]-1H-indene-2-carboxylate; IN-KG433, methyl 5-chloro-2,3,-dihydro-2-hydroxy-1-

[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]-hydrazono]-1*H*-indene-2-carboxylate; and IN-KB687, methyl [4-(trifluoromethoxy)phenyl]carbamate, calculated as the stoichiometric equivalent of indoxacarb in the commodity.

Commodity	Parts per million
Egg	0.20
Poultry, fat	0.20
Poultry, meat	0.06
Poultry, meat byproducts	0.06

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